MULTI-AXIAL POSITIONING SYSTEM FOR A SURGICALLY-IMPLANTED SPINAL SUPPORT

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a surgical procedure for implanting a spinal support and more specifically to a multi-axial system which can be adjusted to the anatomy of the patient, reducing the time required for surgery and reducing stress on the patient.

Description of Related Art

Spinal disorders such as degenerative discs, stenous, trauma, scoliosis, kyphosis and spondylolisthesis are treated by surgical procedures which require screws in the bone portion of the spine connected to a length of rod which is bent to conform to the spinal anatomy of the patient. Various devices and techniques have been proposed which require bending of the rod in the operating room to provide the required anatomical support for the particular patient. In most available systems, however, bending is mandatory. These bends generate stress concentrations and potential failure points which inherently weaken the system. The normal body movements of the patient, over time, may cause the rod or rods to break due to metal fatigue, and a catastrophic failure of the rod will require a further spinal procedure and much risk and inconvenience to the patient. This is a serious problem alleviated by the present invention with the use of pre-formed rods.

Moreover, the competitive rods are repeatedly bent by the surgeon (to accommodate the particular patient's anatomy) in a sort of "coarse and fine" or "cut and try" procedure, which is somewhat time-consuming. Minutes in the operating room translate into many dollars of cost, and even more significantly, a shortened surgical procedure means less patient exposure and risk, a lower infection rate, less anesthesia, and less blood loss for the patient.

U.S. Patent No. 6,478,798 to *Howland* discloses an anchor screw assembly in which the stress and load is placed on a pin and the rod is offset from the axis of the anchor screw.

An improved system is required which reduces the time required for the surgeon to perform the procedure, requires less bending of rods, is less costly, reduces stress and trauma to the patient and wherein the location of the anchor screw is determined by the anatomy of the patient rather than by the nature and location of the rod.

SUMMARY OF THE INVENTION

It is an object of the invention to provide a surgically-implanted spinal support which conforms to the anatomy of the patient.

It is a further object of the invention to provide a multi-axial positioning system which is aligned and adjusted by the surgeon during surgery with minimum adjustments and in reduced time.

It is another object of the invention to provide a less costly system as compared to present systems.

It is still another object of the invention to provide a kit containing a minimum number of components for use by the surgeon in the procedure.

In accordance with the teachings of the present invention, there is disclosed a surgically-implanted spinal support, wherein at least two screws are embedded into a patient's spinal column. Each screw has an axis and each screw carries a pair of clamps tightened by a nut on each screw. The clamps include an upper clamp and a lower clamp having respective cooperating semi-cylindrical slots for receiving a rod therebetween. The rod has an axis. The improvement is a pair of yokes (washers) carried by each screw and including an upper yoke disposed above and adjacent to the upper clamp and further including a lower yoke disposed below and adjacent to the lower clamp. Each of the yokes has a substantially semi-cylindrical seat, and each of the clamps has a substantially semi-cylindrical complementary outer surface engaging the seats of the respective yoke. In this manner, the clamps may swivel in either direction and to a limited degree about an axis which is substantially perpendicular to the axis of the respective screw.

In further accordance with the teachings of the present invention, there is disclosed a multi-axial positioning system for a surgically implanted spinal support embedded into a patient's spinal column. The system has at least one screw, a lower yoke having a semi-cylindrical seat having a first opening therein and an upper yoke having a semi-cylindrical seat having a second opening therein. The screw is received in the first and second openings and projects above the upper yoke. The system has an upper clamp and a lower clamp. Each clamp has a planar inner surface, the inner surface being disposed opposite one another. Each clamp has a semi-cylindrical outer surface, the opposed clamps forming a cylindrical outer surface. Each clamp has a through opening therein, the opposed clamps being disposed in the respective

semi-cylindrical seat of the upper yoke and the lower yoke. The screw passes through the through openings in the clamps wherein the clamps may swivel in either direction to a limited degree within the upper yoke and the lower yoke thereby providing a first axis of positioning. Each clamp has an end distal from the screw. A semi-cylindrical slot is formed in each clamp near the respective end of each clamp. A rod having a length is adjustably received in the semi-cylindrical slots in the clamps, thereby providing a second axis of positioning. Each clamp has a length between the screw and the rod. The length of the clamp is selected to be adapted to the anatomy of the patient's spinal column, thereby providing a third axis of positioning. Each screw is adjustably embedded at a preselected angle and depth into the patient's spinal column thereby providing a fourth axis of positioning.

In still further accordance with the teachings of the present invention there is disclosed a multi-axial positioning system for a surgically implanted spinal support anchored in the bone portion of a patient's spine. A first axis of positioning is formed by a pair of opposing clamps. Each clamp has a semi-cylindrical outer surface and a through opening formed therein. A screw is received in the through openings, wherein the clamps may swivel in either direction and to a limited degree with respect to the screw. A second axis of positioning is formed by a rod, the rod being movably received in a respective slot formed in an end of each of the clamps distal from the screw. A third axis of positioning is formed by a length of each clamp between the screw and the distal end of the respective clamp. A plurality of clamps are provided, each pair of clamps having a length different from the other pairs of clamps. A fourth axis of positioning is formed by the screw being adjustably anchored at a preselected angle and depth into the bone portion of the patient's spine.

Additionally, in accordance with the teachings of the present invention, there is disclosed a spinal surgical procedure in an operating room for implanting a spinal brace between spaced-apart vertebrae. A plurality of spaced-apart screws or other fasteners are anchored in the bone portion of a patient's spine. The screws carry respective clamping means for retaining a rod serving as a brace between vertebrae. The improvement is a multi-axial positioning system for the respective clamps, thereby minimizing the number of loose parts on the sterile field in the operating room, thereby facilitating a quick, convenient and easier implant of the spinal brace by the surgeon, and thereby involving substantially less time and hence less risk to the patient in the operating room while substantially reducing overall costs.

Also, in accordance with the teachings of the present invention, there is disclosed a method of surgically implanting a spinal support in a bone portion of a spine of a patient. There is provided a plurality of screws, a plurality of pairs of clamps, the pairs of clamps having lengths different from other pairs of clamps, a plurality of upper yokes and a plurality of lower yoke, a plurality of nuts, and a plurality of rods, the rods having differing lengths and differing curvature. The patient is prepared for surgery. The patient is incised to expose the bone portion of the spine of the patient which is in need of repairs. At least two screws are inserted into the bone portion at a spaced-apart distance, a depth and an angle required to treat the patient. Lower yokes are disposed on each of the screws. A selected pair of clamps are disposed on each of the screws. Each pair of clamps is seated in a respective lower yoke. Upper yokes are disposed on the respective screws, each pair of clamps being seated in a respective upper yoke. A respective nut is disposed on each screw and partially tightened to secure the upper yoke loosely on the clamps. A selected rod is disposed into longitudinal slots on the ends of the clamps distal from the screws. The selected rod is moved axially within the longitudinal slots while swivelling the clamps within the upper and lower yokes such that the rod connects the at least two pairs of clamps and the rod is disposed substantially parallel to and conforming to the bone portion of the spine of the patient. The degree of swivel and length of the clamps are adjusted, the axial movement of the rod is adjusted to align the rod with the spinal column anatomy. The nut is tightened to secure the components in the desired relative positions.

These and other objects of the present invention will become apparent from a reading of the following specification taken in conjunction with the enclosed drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a patient undergoing the surgically implanted spinal support.

FIG. 2 is a perspective view of a spinal support of the prior art.

FIG. 3 is a perspective view of a different spinal support of the prior art.

FIG. 4 is a perspective view of the spinal support of the present invention.

FIG. 5 is an exploded perspective view of the screw, lower yoke, lower clamp, upper clamp, upper yoke, nut and rod.

FIG. 6 is a side elevation view of the lower yoke.

FIG. 7 is a bottom plan view of the lower yoke.

FIG. 8 is a top plan view of the lower yoke.

FIG. 9 is an end view of the lower yoke.

FIG. 10 is a side elevation view of the upper yoke.

FIG. 11 is a top plan view of the upper yoke.

FIG. 12 is a bottom plan view of the upper yoke.

FIG. 13 is an end view of the lower yoke.

FIG. 14 is a side elevation view of the nut.

FIG. 15 is a top plan view of the nut.

FIG. 16 is a top plan view of a clamp.

FIG. 17 is an end view of the clamp of FIG. 16.

FIG. 18 is a cross-section view taken across the lines 18-18 of FIG. 16.

FIG. 19 is a bottom plan view of the clamp of FIG. 16.

FIG. 20 is a front elevation view of the yokes holding the clamps on the screw.

FIG. 21 is a top plan view of FIG. 20.

FIG. 22 is a cross-section view taken across the lines 22-22 of FIG. 21.

FIG. 23 is a side elevation view of the yokes holding the clamps on the screw.

FIG. 24 is a top plan view of FIG. 23.

FIG. 25 is a cross-section view taken across the lines 25-25 of FIG. 24.

FIG. 26 is a perspective view of the spinal support showing swiveling of the clamp 15° in a first direction.

FIG. 27 is the view of FIG. 22 showing swivelling of the clamp 15° in a second opposite direction.

FIG. 28 is a perspective view of the spinal support showing lateral movement of the clamp.

FIG. 29 is a perspective view showing a tool crimping the upper yoke to the nut.

FIG. 30 is a perspective view of the crimped upper yoke securing the nut.

FIG. 31 is a perspective view of a kit containing components for use in an operating room.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1, the patient is placed in the operating room (O.R.) so the surgical team has ready access to the patient's spine. An incision is made to expose the bone and the spinal support is surgically implanted as will be described.

FIGS. 2 and 3 show spinal implants of the prior art. A plurality of spaced-apart screws 10 are driven into the bone portion of the patient's spinal column. The screws may be self-tapping. At the upper end of each screw 10, there is a spacer or clamp 12. The clamp 12 may be a pair of opposing members. The clamp 12 is secured to the screw 10 with a nut 14. A reinforcing rod 16 is mounted between the pair of clamps 12 and the rod 16 connects clamps on the spaced-apart screws. The rods 16 preferably are formed from titanium and usually are bent during the surgical procedure to conform to the anatomy of the individual patient. As previously noted, bending of the rods may result in failure of the surgical procedure. In most prior art spinal supports, the rods are 5-10 inches in length. The spinal implant usually consists of two rows of screws and rods, each row being on opposite sides of the spinal column.

The spinal implant of the present invention, as shown in FIG. 4 differs from the prior art in that it is multi-axial in positioning as will be described.

As seen in FIG. 5, the lower portion of the body of the screw 10 has a relatively coarse thread and is threaded into the bone portion of the patient's spinal column. The screw 10 is inserted at a preselected angle to engage a significant thickness of the spinal column to assure a secure anchoring of the spinal implant. The angle may vary from patient to patient. Also, the depth of the insertion of the threaded portion of the screw 10 is determined by the anatomy of the patient since maximum depth is desired consistent with absence of potential injury to the spinal cord. A flange 22 is formed on the screw 10 immediately above the coarse threaded portion of the body of the screw 10. The portion of the body of the screw 10 immediately above the flange is formed having at least two parallel opposite sides 24 which extend upwardly from the flange 22. The parallel sides 24 are oriented substantially parallel to the vertical axis of the spine of the patient. The remaining portion of the body of the screw 10 is formed with a thread 25 thereon from the upper reach of the parallel sides 24 to the end of the screw 10. Seated on the flange 22 is the lower yoke 18 (FIGS. 6-9). The lower yoke 18 has an opening 26 in the center. The opening 26 has at least two parallel opposite sides which cooperate with the body of the screw 10 such that when the screw 10 is received in the opening 26 in the lower yoke 18, the

lower yoke 18 is supported by the flange 22 and the lower yoke 18 cannot rotate about the screw 10. Also, the orientation of the cooperating parallel opposite sides 24 of the body of the screw 10 and the opening 26 in the lower yoke, assure that the clamps 12 extend outwardly from the screw 10 in the desired direction as related to the anatomy of the patient as will be described. The lower yoke 18, has two arms 28 on opposite sides of the lower yoke 18, extending upwardly from the lower face of the lower yoke 18 forming a substantially semi-cylindrical seat 30 within the lower yoke 18.

As shown in FIGS. 10-13, an upper yoke 20 has an opening 32 in the upper face, the upper body of the screw 20 is received in the opening 32. The upper yoke 20 has two arms 34 extending downwardly toward the arms 28 on the lower yoke 18. The arms 34 on the upper yoke 20 are on opposite sides of the upper yoke and form a substantially semi-cylindrical seat 36 which is opposite from the substantially semi-cylindrical seat 30 in the lower yoke 18. Together, there is formed a cylindrical seat between the lower yoke 18 and the upper yoke 20. In the top face of the upper yoke 20, there is formed a recess 38 which has a depth terminating in a radially inwardly projecting annular shelf.

The nut 14 has a threaded through opening 40 which cooperates with the threaded upper portion of the body of he screw. It is preferred that the nut 14 have at least one slot formed therein to facilitate tightening and loosening of the nut 14 with a tool such as a screwdriver.

When the nut 14 is threaded into the threaded upper body 25 of the screw 10, the nut is seated in the recess 38 in the top face of the upper yoke 20. The depth of the recess is approximately equal to the height of the nut 14 such that the top of the nut 14 is approximately flush with the top surface of the upper yoke 20. In a preferred embodiment the nut 14 is received in the recess 38 and the top surface of the upper yoke 20 is rolled to retain the nut 14. This is done during the manufacture of the components so there are fewer parts for the surgeon to account for during the surgical procedure.

FIGS. 18-19 show one of the clamps 12. The other clamp 10 is identical thereto and the clamps 12 are interchangeable. Each clamp 12 has an inner planar surface 44 and a semi-cylindrical outer surface 46. A through opening 48 is formed near an end of each clamp 12. The opening 48 has a diameter larger than the diameter of the body of the screw 10 and is elongated in axis perpendicular to the length of the clamp 12. Distal from the opening 48 in each clamp, a semi-cylindrical slot 50 is formed on the inner planar surface 44 perpendicular to the length of

the clamp. Preferably, a plurality of ribs 52 are formed longitudinally in the slot 50 as will be explained. The clamps 12 are always provided as a pair, each member having the same length. However, the length of the clamps 12 may be varied so that longer pairs and shorter pairs are available. This provides a flexibility to the positioning of the clamps 12 to better conform to the anatomy of the patient.

As shown in FIGS. 20-25, the clamps 12 are disposed with the planar surfaces 44 adjacent to one another, the respective openings 48 aligned and the semi-cylindrical slots 50 opposed to one another forming a cylindrical opening distal from the screw 10. Preferably, the inner surfaces of the clamps have roughened to provide friction between the surfaces and to deter movement.

A length of the rod 16 is received in the cylindrical opening formed between the slots in the distal ends of the clamps (FIG. 4). The rod 16 is connected to the respective clamps 12 on the spaced-apart screws 10. Preferably, the rod 16 has a plurality of ribs formed thereon which extend longitudinally the length of the rod 16 and are circumferentially around the rod 16. The ribs on the rod 16 cooperate with the ribs 52 in the slot 50 on the clamps 12 such that rotational movement of the rod 16 with respect to the clamps is prevented. During the surgical procedure the rod 16 is placed in the lower clamp 12 before the upper clamp is secured which reduces the time of the operation and greatly simplifies the disposition of the components. Further the rods preferably have a length of about 4 inches and are provided as a set, each rod 16 having a different pre-bent curvature (with different radii). The purpose is to eliminate or to minimize the bending of the rod in the operating room during the surgical procedure.

Because of the cylindrical form of the adjacent clamps 12 disposed within the cylindrical seat between the upper yoke 20 and the lower yoke 18 and the elongated opening 48 in each clamp, the pair of clamps can be swivelled in either direction within the cylindrical seat (FIGS. 26-27). The swivel action is about an axis which is substantially perpendicular to the axis of the screw 10. The clamps may swivel approximately 15° in either direction for a total excursion of approximately 30°. This swivelling ability provides an axis of positioning for the spinal support to adapt the spinal support to the anatomy of the patient.

Also, because the through openings 48 in the clamps 12 have a diameter greater than the diameter of the screw 10, the clamps 12 may be moved, to a limited extent, in a plane perpendicular to the axis of the screw 10. This incremental sliding movement provides a "fine

tuning" to the effective length of he pair of clamps 12 and provides for a further axis of positioning for the spinal support (FIG. 28).

If desired, after the spinal support system has been surgically implanted in the bone portion of the patient's spine, the nut 14 on each screw 10 may be locked in place to prevent any back-off. As shown in FIGS. 29-30, the upper yoke 20 is crimped with a tool 56 to produce an inward projection 58 within the slotted portion of the nut 14. This projection 58 prevents rotation of the nut 14.

The components minimally required in the operating room for performing the spinal surgery are shown in FIG. 31. A container 54 is provided having a plurality of screws 10, clamps 12, upper yokes 20, lower yokes 18, nuts 14 and rods 16 to constitute a kit. The yokes 18 and 20 may be provided separately or the lower yoke 18 may be preassembled or the screw 10 and the nut 14 may be retained in the upper yoke 20. The clamps 12 are pairs with different lengths and the rod 16 may have different curvatures. The number of individual components may be varied from kit to kit but the total number of components is significantly less than those required in presently available technology. This kit reduces the time the surgeon needs to perform the surgery. The reduction in the bending of he rods further shortens the time of the operation. As a result, there is less stress and trauma on the patient. Also, the costs for components is reduced as compared to present technology.

The procedure used by the surgeon is to have at least one kit 54 of components, or a plurality of individual components available in the operating room. The patient is prepared for the surgery and an incision is made to expose the bone portion of the patient's spine which is in need of repair. At least two screws 10 are inserted into the bone portion of the spine. The screws 10 are spaced apart a distance and are inserted at an angle and to a depth which is required to treat the individual patient. Lower yokes 18 are disposed on each screw 10. At least two pairs of clamps 12 are selected to be disposed on the at least two screws and the clamps are seated in the respective lower yokes 18. The lengths of each pair of clamps 12 is determined by the anatomy of the individual patient. An upper yoke 20 is disposed on each screw such that the pair of clamps 12 are seated in the upper yoke on each respective screw. A nut 14 is disposed on each screw 10 and the nut is partially tightened to secure the respective upper yokes loosely on the clamps 12. A rod 16 is selected which has a desired curvature. The rod 16 is disposed in semi-cylindrical slots 50 formed in the clamps distal from the screws. The rod 16 is moved

axially within the semi-cylindrical slot while swivelling the clamps within the upper and lower yokes such that rod connects the at least two pairs of clamps. The rod 16 is disposed substantially parallel to and conforming to the bone portion of the spine of the patient. The rod may be further bent as required. The clamps and rod are axially positioned to align the rod with the bone portion of the patient's spine. The nut 14 is tightened to secure the components in the desired relative positions. If desired, the upper yoke may be crimped to prevent rotation of the nut.

The clamps 12 may be color coded to indicate different lengths of the clamps. The color code simplifies the procedure for the surgical team. Each member of a pair of clamps 12 is identical so that either clamp of the pair may be the upper or the lower clamp. This reduces the number of components and eliminates possible mismatch. The swivelling and sliding movement of the clamps provides axial positioning which was achieved in prior devices with a ball joint.

The present device is easy for the surgeon to use because the clamps may be separated to place the rod in the semi-cylindrical slot as opposed to a "C" shaped opening in prior devices. The surgeon can place the rod in the open clamp and does not need to thread the rod through the opening. Because of this, the location of the screw in the bone portion of the spine is determined by the anatomy of the patient. In prior devices, the curvature of the rod determined the location of the anchoring screw.

The present device provides a multi-axial positioning system. The clamps may swivel in either direction between the upper yoke and the lower yoke. The rod has a length which may be adjustably received in the distal ends of the clamps. The clamps are provided in different lengths and may be selected to be adapted to the anatomy of the patient's spinal column. The clamps may further be slid perpendicularly with respect to the screw. Each screw is adjustably imbedded at a preselected angle and depth into the patient's spinal column.

Obviously, many modifications may be made without departing from the basic spirit of the present invention. Accordingly, it will be appreciated by those skilled in the art that within the scope of the appended claims, the invention may be practiced other than has been specifically described herein.